

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

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PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing
(day/month/year)

13 -07- 2005

Applicant's or agent's file reference

159885 TG-KR

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/NO2005/000012

International filing date (day/month/year)

10.01.2005

Priority date (day/month/year)

12.01.2004

International Patent Classification (IPC) or both national classification and IPC

A61K 35/84 // A61P 31/00, A61P 37/08, A61P 33/00

Applicant

Geir Hetland

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further opinions, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language, _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

- ☐ a sequence listing
☐ table(s) related to the sequence listing

b. format of material

- ☐ in written format
☐ in computer readable form

c. time of filing/furnishing

- ☐ contained in the international application as filed.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

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WRITTEN OPINION OF THE
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International application No.

PCT/NO2005/000012

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	<u>2-4, 7-10</u>	YES
	Claims	<u>1, 5-6</u>	NO
Inventive step (IS)	Claims	<u>3-4</u>	YES
	Claims	<u>1-2, 5-10</u>	NO
Industrial applicability (IA)	Claims	<u>1-10</u>	YES
	Claims	<u></u>	NO

2. Citations and explanations:

The subject-matter of the claims are directed to the second medical use of *Agaricus blazei* Murill to be used in the prevention and treatment of bacterial and non-bacterial infections as well as preventing allergy.

Reference is made to the following documents:

D1: Database WPI, AN 2003-785658 & KR 2003021096
D2: Osaki Yoshiko, Yakugaki Zasshi, jun 17, 1994, Vol.114, No.5, p342-350
D3: STN International, CAPLUS acc.no. 2001:461386.
D4 Sorimachi Kenji et al., Biosci. Biotechnol. Biochem., 2001, Vol.65, No 7, p. 1645-1647.
D5: EP 0413053
D6: WO01/85191

D5 discloses the use of a substance which is obtained from the mycelium of an edible mushroom, i.a. *Agaricus blazei* Murill, as a drug for preventing allergies (see page 5, lines

.../...

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

34-35, claims 1 and 9). D6 discloses a substance which is extracted from body tissues or mycelia tissues of *Agaricus blazei* which substance is an allergy cell activity inhibitor. It is thus known to use *Agaricus blazei* for preventing allergies. Claims 1, 5-6 are therefore not novel. Claims 7-10 are considered as being obvious modifications which are not considered to involve any inventive step.

It is not known from the prior art that *Agaricus blazei* Murill is useful for treating bacterial infections caused by a parasite or a virus. As however there is no experimental data in the application showing that *Agaricus blazei* Murill is able to show an effect on non-bacterial infections such as infections caused by parasites or viruses, claim 2 is not sufficiently disclosed (see Box VIII). Claim 2 lacks an inventive step.

D1, D2, D3 and D4 disclose that the fungus *Agaricus blazei* has antibacterial effect but do not disclose that the fungus has activity against pneumococcus.

Claims 3-4 are novel and are considered to involve an inventive step.

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Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawing or on the question whether the claim are fully supported by the description, are made:

Claims 1-2 and thereof dependent claims 6-10 are not supported by the description as required by Article 6 PCT, as their scope is broader than justified by the examples provided in the description. The reasons therefore are the following: in the application, technical data was provided showing effect against infections caused by pneumococci and against allergy. However no data was provided showing that *Agaricus blazei* Murill has effect against non-bacterial infections such as infections caused by parasites and virus.

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